UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,619	08/10/2001	Wilson Burgess	061525-5005	2963

9629 7590 02/15/2005

MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
CHORBAJI, MONZER R	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 02/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,619	BURGESS ET AL.	
	Examiner	Art Unit	
	MONZER R CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/28/02; 4/18/02; 8/26/02; 11/30/03; 2/25/03; 4/1/03; 6/5/03; 9/25/03; 3/3/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This general action is in response to the application filing date of 08/10/2001

Claim Objections

1. Claims 22-73 are objected to because of the following informalities: the numbered claim 22 should be re-numbered as 23. As a result, the rest of the originally numbered claims have been changed. Proper re-numbering of the claims is needed.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-29, 31-34, 38-39, 41-50, 52, 56-66 and 68-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hackett (WO 91/16060) in view of Hanna et al (Free Rad. Res. Comms-IDS)

With respect to claims 1-3 and 57, the Hackett reference discloses a method and a composition for inactivating biological fluids (page 3, lines 1-5 and examples on pages 22-26) including the following: reducing the residual solvent content of the biological material (page 4, lines 25-27) then adding an amino acid stabilizer (page 4, lines 3-4, page 5, lines 15-17, page 7, lines 10-11 and page 17, lines 5-7) to the material at an intrinsic amount to protect the material such that the solvent reducing step, or the addition step (page 3, lines 16-19 and page 18-25) or the temperature reducing step (equivalent to the freezing step in the solvent reduction process) can be done in reverse order . The Hackett reference goes on to irradiate the biological material at both effective intrinsic rate and time in order to inactivate such a material. The advantages recited of either reducing the residual solvent and the amount of the amino acid added or lowering the temperature and the amount of the amino acid added are all intrinsic features of the Hackett reference (page 3, lines 19-23) since the teaching of adding amino acids is inclusive of adding polypeptides, dipeptides, or peptides; however, with respect to claims 1-3 and 57, the Hackett reference fails to explicitly disclose adding a dipeptide. The Hanna reference teaches that the dipeptide carnosine does protect

biological materials (preserve) when added in combination with an irradiation step (page 265, lines 1-4). Thus, it would have been obvious to one having ordinary skill at the time the invention was made to modify the method and composition of the Hackett reference by substituting one type of amino acid for another since carnosine is known to protect irradiated biological material as evidenced by Marta reference on page 265, lines 1-4.

With respect to claims 4-7, the Hackett reference teaches re-suspending the biological material in an organic solvent after reducing the amount of water (page 4, lines 25-27 and page 10, lines 13-25).

With respect to claims 8-16, the Hackett reference provides, for example, on page 15, lines 10-16, intensity and time ranges for irradiating the biological material. Upon unit conversion, the radiation rates were found to fall between 1.80 and 25 kGy/hour for a 6-log microorganism reduction. However, depending on the degree of inactivation intended and the sensitivity of biological materials modifying such a teaching is a matter of routine experimentation.

With respect to claims 17-28 and 60-66, the Hackett reference teaches maintaining the biological material in a low oxygen atmosphere (vacuum) that includes a noble gas using a vacuum (page 9, lines 21-25). The Hackett reference does not teach using argon, but does teach that other noble gases can be used instead of nitrogen. As a result, choosing a specific noble gas is a matter of choice of design that is within the scope of the artisan. The Hackett reference further uses lyophilization process and provides a range for the residual solvent (page 5, lines 4-8).

With respect to claim 41, the Hanna reference teaches using carnosine (page 265, lines 1-3).

With respect to claims 29, 31-34, 38-39, 42-50, 52, 56, 58-59 and 68-72, the Hackett reference discloses the following: adding a sensitizer prior to irradiating a biological material (page 3, lines 18-20) that includes a pathogen such as viruses, adding an additional stabilizer prior to irradiating (page 20, lines 1-4), adding an antioxidant (page 20, line 1), an additional stabilizer that reduces damage due to reactive oxygen species (page 20, lines 1-4) such as glutathione (page 20, line 1) that is also known to act as an oxygen scavenger, using electromagnetic radiation (gamma radiation is an example of electromagnetic radiation, page 15, line 11), using ultraviolet light (page 15, line 14), using gamma radiation (page 20, line 1) , using x-ray beam radiation (page 21, lie 5), irradiating at ambient temperature (page 24, lines 16-18), irradiating at above ambient temperature such 26 degrees Celsius (page 24, lines 16-17), reducing the amount of the solvent that is effective for preserving the biological material (page 9, lines 21-32), the biological material includes Factor VIII (page 2, lines 22-25) and the concentration of the biological material is 10% (page 15, line 8) . Further, the Hackett reference teaches that other types of radiation can be used, such that one having ordinary skill in the art would recognize substituting one conventional radiation for another upon reading the teaching in the Hackett reference (page 21, lines 4-6)

With respect to claim 41, the Marta reference teaches using carnosine (page 265, lines 1-3).

6. Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hackett (WO 91/16060) in view of Hanna et al (Free Rad. Res. Comms-IDS) and further in view of Wiesehalm et al (U.S.P.N. 4,727,027).

With respect to claims 35-37, both the Hackett reference and the Hanna reference fail to add a combination stabilizer to the biological material; however, the Wiesehalm reference, which is in the art of decontaminating biological compositions, teaches adding heparin to the calf serum (col.11, lines 31-33). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Hackett reference by adding heparin in order to control any activated clotting factors present in the calf serum as taught by the Wiesehalm reference.

7. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hackett (WO 91/16060) in view of Hanna et al (Free Rad. Res. Comms-IDS) and further in view of Stogniew et al (U.S.P.N. 6,258,821).

With respect to claim 40, both the Hackett reference and the Hanna reference fail to teach adding mixtures of two or more of the recited additional stabilizers in claim 40; however, the Stogniew reference, which is in the art of stabilizing compounds against degradation caused by light and heat, teaches that propyl gallate and ascorbic acid can be added together to the compositions. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Hackett reference to include antioxidants such as propyl gallate and ascorbic acid as

taught by the Stogniew reference since ascorbic acid when added exhibit stability against light exposure (col.7, lines 3-5).

8. Claims 30, 53-55 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hackett (WO 91/16060) in view of Hanna et al (Free Rad. Res. Comms-IDS) and further in view of Purdum (U.S.P.N. 6,808,638).

With respect to claims 30, 53-55 and 67 both the Hackett reference and the Hanna reference fail to teach the following: prion as a pathogen, irradiation below ambient temperature, irradiation below the freezing point of the biological material, irradiation below the eutectic point of the biological material and the biological material being glassy or vitrified. The Purdum reference, which is in the art of treating blood components, teaches the following: prion as a pathogen (col.14, lines 7-8), applying ultrasonic energy to cooled biological material, i.e., below ambient temperature (col.6, lines 43-45), applying ultrasonic energy to biological material being below its freezing point (col.7, lines 53-58 and col.8, lines 26-36), applying ultrasonic energy to biological material being below its eutectic point (col.10, lines 35-38 and lines 43-46) and the biological material being glassy or vitrified (col.10, lines 34-38). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Hackett reference by adding the ultrasonic irradiation step as disclosed by the Purdum reference since such energy reduces the effective viscosity of the fluid and improves heat transfer within the fluid (col.10, lines 43-47).

9. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hackett (WO 91/16060) in view of Hanna et al (Free Rad. Res. Comms-IDS) and further in view of Platz et al (U.S.P.N. 6,828,323).

With respect to claim 51, both the Hackett reference and the Hanna reference fail to teach the concept of combining wavelengths of visible and UV light; however, the Platz reference, which is in the art of irradiating biological compositions, teaches combining visible and UV sources as one source emitting wavelengths covering both the visible light range and the ultraviolet light range (col.15, lines 60-63). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Hackett reference by substituting a combined energy source for single source as taught by the Platz reference in order to be able to irradiate far greater number of various different types of biological compositions without the need to switch energy sources.

10. Claims 73-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hackett (WO 91/16060) in view of Hanna et al (Free Rad. Res. Comms-IDS) and further in view of Fike et al (U.S.P.N. 6,383,810).

With respect to claims 73-76, both the Hackett reference and the Hanna reference fail to teach concentration ranges above 10% for the biological material present in a composition; however, the Fike reference, which is in the art of producing sterile biological compositions, teaches that serum containing composition can be 15%, or 20%, or 50% or higher (col.14, lines 55-59). Thus, it would have been obvious to one having ordinary skill at the time the invention was made to modify the composition of the

Hackett reference to include various higher concentration ranges of the biological material since such a modification is a matter of routine experimentation depending on the intended use as evidenced by the Fike reference.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Sakai reference (Microbiological Studies on Drugs and Their Raw Materials. IV. Sterilization of Microbial Contaminants in Enzyme Powder by Gamma Radiation-IDS) teaches adding cysteine, which is a dipeptide to biological compositions then irradiating.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monzer R. Chorbaji MRC
Patent Examiner
AU 1744
01/27/2005

Robert J. Warden, Sr.
ROBERT J. WARDEN, SR.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700